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EXAMINER
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LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,081

Applicant(s)

SKEEN, JAY

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003 and 08 March 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 17, 18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/15/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

1. Claims 1 and 18 are objected to because of the following informalities: "titration" is misspelled. Appropriate correction is required.
2. Claims 1-4, 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
3. There is no teaching in the specification that the legs should be used to avoid mixing of contents as in claims 1 and 20 or what structure would be used or steps would be taken to avoid mixing.
4. The amendment filed September 25, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as explained above.
5. Applicant is required to cancel the new matter in the reply to this Office Action.
6. This application repeats a substantial portion of prior Application No. 09/385519, filed Aug 30, 1999, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

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7. ~~7.~~ Claims 1-4, 18, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claims 1 and 18, "all of said open distal ends... micro-titration plate" is unclear because the sizing is described relative to wells, which are not positively recited elements of the invention. In claims 1 and 20, it is not clear what structural limitations are intended by the statements of intended use to avoid mixing.

9. ~~9.~~ The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10. A person shall be entitled to a patent unless –

11. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. ~~12.~~ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

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which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. ~~4.~~ The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

14. Determining the scope and contents of the prior art.
15. Ascertaining the differences between the prior art and the claims at issue.
16. Resolving the level of ordinary skill in the pertinent art.
17. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. ~~5.~~ Claims 1, 4, 18, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Treptow et al.

19. Treptow teaches a pipette tip having two conical tips extending from a single tubular body for receiving sample and reagent separately into the same pipette tip (Figure 11; col. 5, lines 31-33). No membrane is shown in Figure 11. An opening 13 is provided, which is structurally capable of attaching to different pipettes with different plunger lengths. The tips are structurally capable of fitting together or separately in wells of suitable size.

20. ~~6.~~ Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Treptow et al. as applied to claims 1, 4, 14, 18-20 above, and further in view of Goodman.

21. Treptow fails to teach four tips on one pipette tip or explicitly teach fitting all the channels in one well and individual wells.

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22. Goodman teaches a pipette tip having tubular body 37, 65 in pressure communication with tips 23 via membrane 19, , which can be provided in pairs (Figure 1) or fours (Figures 20, 21). The tips are structurally capable of fitting together in well 25 or separately in wells 57 of suitable size. In this rejection, claim 1 has been interpreted to agree with claim 15, i.e., to have a membrane.

23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide four conical tips on the device of Treptow in order to simultaneously pipette four reagents into a common tip device as an alternative to two reagents as taught by Goodman.

24. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

25. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

26. Claim 17 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 6338825. This is a double patenting rejection.

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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28. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

29. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6338825 in view of Treptow.

31. The patented claim teaches the invention of instant claim 2 with the exception of the negative limitation precluding a membrane.

32. The teachings of Treptow are given above.

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pipette tip of the patented claim without a membrane as taught by Treptow in order to permit free movement of air into and out of the top of the tip as displaced by the piston (col. 4, line 65).

34. Applicant's arguments, see arguments, filed March 8, 2004, with respect to Goodman have been fully considered and are persuasive. The rejection of claims based on Goodman as a primary reference has been withdrawn.

35. The examiner notes that in view of the specification and applicant's arguments, "communication" is being interpreted as "flow communication" to define over the pressure communication via membrane of Goodman.

36. Applicant's arguments filed March 8, 2004 have been fully considered but they are not persuasive.

37. With respect to the rejections under 35 USC 112, first paragraph, the limitation to "keeping the contents... form mixing" is still in the claims. There is no mention one way or the other with regard to mixing in the specification. Applicant has not pointed out the support for this limitation, and the examiner finds none.

38. Applicant has not fully addressed the rejection under 35 USC 112, second paragraph.

39. Applicant argues that Treptow teaches using the pipette tip as a reaction chamber, but points to no structural limitation in the instant claims that defines over the structure of Treptow, regardless of the intended use of Treptow. Applicant argues that the short conical tips of Treptow are designed to mix reagents, but fails to point to any structural limitation in the claims that defines over the structure of Treptow. Note that the functional limitation in the instant claims directed to prevention of mixing constitutes new matter. Further, the functional limitation in the instant claims is directed to intended use, e.g., aspirating a volume smaller than the volume of the individual tips so as to prevent the volume aspirated from extending above the top of the legs and into the pipe body. Note also, that whether the contents of the individual tips in Treptow are mixed in the body portion is also a question of the method of use (e.g., amount aspirated, whether the tip is mechanically moved to provide mixings) and the instant claims are directed to an apparatus claim.

40. Applicant has not overcome the obviousness-type double patenting rejection of claim 2. Note that a new double patenting rejection with respect to claim 17 as amended has been made.



41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
42. Hanaway et al. teach a multi-pipettor that uses an actuator mounted at member 30 as shown in Figure 8 to produce pressure differences in a cavity above a pipette array.
43. Crandall teaches a multi-outlet pipette head that mounts via tubular member 78.
44. Wilson teaches a pipette tip 28 with tubular body 32 and channels 42.
45. Stahli teaches a pipette tip, e.g., with tube 146 and channels 147 (Figure 11).
46. Fisher teaches a pipette tip manifold 21-169-10E with a mounting end and open channels.
47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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48. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

49. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

50. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

Jml  
May 30, 2004.